

Dean L. Engelhardt et al.
Serial No. 08/046,004
Filed: April 9, 1993
Page 2 (Request for Reconsideration of Restriction Requirement
(And Election of Species) Under 37 C.F.R. §1.143-June 23, 1994)

REMARKS

Reconsideration of the restriction requirement and the election of species is respectfully requested.

Claims 204-233 are presently pending in the application having been made subject to an invention restriction and a species election requirement.

The Restriction Requirement Under 35 U.S.C. §121

In the Office Action (page 2), the Examiner required restriction to one of the following groups:

- I. Claims 204-227 and 233, drawn to a nucleotide, classified in Class 536, subclass 23.1; and
- II. Claims 228-232, drawn to a composition, classified in Class 435, subclass 6.

The Examiner stated:

Inventions Group I and Group II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the nucleotide of Group I can be used in detection processes other than in the composition of Group II. For example, a reaction in which the nucleotide is involved could be detected directly as with a fluorescent moiety without the need for the formation of a complex.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art, as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicants hereby elect, with traverse, Group I, claims 204-227 and 233, drawn to a nucleotide. Applicants respectfully request that the restriction requirement under 35 U.S.C. §121 be reconsidered and withdrawn in view of the remarks set forth below.

Enz-5(D6)(C1)

At the outset and before addressing the requirement, Applicants and their attorney respectfully point out that extraordinary efforts have been undertaken in this family of patents to maintain a line of demarcation between what could be reasonably construed as separate inventions. In fact, no less than eight divisional applications have been filed, all of which are based upon the priority document, U.S. Application Serial No. 06/391,440 (filed on June 23, 1994).

Applicants respectfully submit that the claims represented by Groups I and II form a single general inventive concept which should properly be examined in the same application. Applicants contend that a diligent search of the art for either one of these two groups, as classified by the Examiner, would necessitate a review of the art - at least in part - for the other corresponding group.

Under MPEP §803, two criteria are necessary in order for a restriction requirement between patentably distinct inventions to be proper:

- (1) The inventions must be independent or distinct as claimed;
and
- (2) there must be a **serious burden** on the Examiner if restriction is not required.

It is respectfully submitted that a search of the prior art to include the composition (defined by claims 228-232) with the nucleotide (defined by claims 204-227 and 233), would not place a serious burden on the Patent Office or the Examiner in light of the search that will already be required for the provisionally elected nucleotide claims. All of claims 204-233 ultimately recite a nucleotide *per se*, or a composition comprising an oligo- or polynucleotide that includes at least one such instantly recited nucleotide. To require restriction in this instance, will - in effect - hamper the current prosecution because it draws attention away from the single general inventive concept unifying all the pending claims, including the instant nucleotide and the composition comprising such a nucleotide.

Furthermore, even assuming for the sake of argument, that the subject matter of claims 228-232 (Group II), would entail, for example, a separate classification or status in the art from the subject matter of provisionally elected claims 204-227 and 233 (Group I), Applicants are firmly of the opinion that such a search, diligently undertaken, would

inevitably overlap with the subject matter covered by the latter. Because the Examiner is expected to and will no doubt carry out a diligent search of the prior art, Applicants submit that no serious burden would be imposed in terms of the search effort if she properly includes the subject matter of Group II with the subject matter of Group I - because both groups define subject matter pertaining to the nucleotide *per se*, or to a composition (oligo- or polynucleotide) that includes the instant nucleotide.

It is submitted, moreover, the instant restriction requirement will only serve to duplicate the search efforts of the Patent Office and other examiners in future filings necessitated by the requirement, in the event it is maintained. The instant Assignee will also be burdened unfairly by the additional cost for such future filings, the subject matter of all of which should be properly examined in the instant divisional application. As noted above, the present and former assignees have already incurred considerable costs in the pursuit of the several divisional applications and the original parent application. The pursuit of these divisional applications numbering eight in all followed in part the original restriction requirement set forth in the September 21, 1983 Office Action issued for the priority application (Serial No. 06/391,440) wherein restriction to one of fourteen (14) groups was required. Further restriction will be patently unfair in this instance where compliance with an earlier requirement has largely been implemented, resulting in the eight divisional applications and a "parent" application.

Applicants sincerely believe that if the Examiner carefully considers the arguments above, she too, will reasonably conclude that no serious burden in terms of search efforts will be placed upon the Patent Office or herself, if the claims of Group II are properly examined in this application, together with the elected claims of Group I. Applicants earnestly urge, therefore, that the Examiner reconsider and withdraw the restriction requirement on the basis of the foregoing remarks.

The Election of Species Requirement Under 35 U.S.C. §121

In the Office Action (pages 2-3), the Examiner stated that "claim 204 is generic to a plurality of disclosed patentably distinct species comprising the nucleotides of claims 209, 210, 212, 215, 217, 218, 219, 221, 223 and 227.

Enz-5(D6)(C1)

Applicants hereby elect, with traverse, the species wherein the Sig component comprises an enzyme. It is respectfully requested, however, that the election of species requirement be reconsidered and withdrawn in view of the following remarks.

Applicants' undersigned attorney has reviewed the pending claims, and it appears that the elected species, Sig comprising an enzyme, is consonant with the elected claims of Group I, as set forth above. Claims 204-208, 211 and 225-227 appear to be generic to the elected species.

Applicants note that the instant invention is directed to a unique and unobvious nucleotide and to an oligo- or polynucleotide and other compositions including such nucleotide. It is respectfully submitted that the species of the detectable Sig moiety, which are disclosed and claimed in the instant application, form a single general inventive concept, when read in context with all of the pending claims and the instant disclosure. Moreover, the species for the detectable Sig moiety represent a reasonable number of species for the members of the group having characteristics in common, such that the generic subject matter for these members - and not single individual species - should properly be examined in the same application. See, for example, the Markush members recited in claims 209 and 232. In addition, Applicants contend that if the species recited in the generic claims, 204-208, 211 and 225-227, are allowed, then the other species will also be found allowable as part of the generic claims. Applicants further contend that they are entitled to claim their invention as broadly as the prior art permits, commensurate with the disclosure requirements of 35 U.S.C. §112. Under such a well-established legal principle, Applicants are entitled to claim and to pursue the full breadth of their generically disclosed invention in the same application. Applicants request, therefore, that the Examiner reconsider and withdraw the species election, and examine the instant claims as originally filed in this application. Moreover, the withdrawal of both the restriction requirement and election of species would comport with the prosecution of the parent application, Serial No. 07/532,461, where no such requirements were required.

Dean L. Engelhardt et al.
Serial No. 08/046,004
Filed: April 9, 1993
Page 6 (Request for Reconsideration of Restriction Requirement
(And Election of Species) Under 37 C.F.R. §1.143-June 23, 1994)

Submission of Information Disclosure Statement

In order to comply with their duty of disclosure under 37 C.F.R. §1.56, Applicants and their attorney intend to file an Information Disclosure Statement as soon as an indication has been received that the instant application has been revived. In this way, the Deputy Assistant Commissioner's office will not be burdened by the vast number of documents (numbering more than sixty) which have been cumulatively cited in either the instant specification, prior prosecution or by other examining authorities.

In view of the foregoing remarks, Applicants respectfully request reconsideration and withdrawal of both the restriction requirement and the election of species. Full examination of claims 204-233 on the merits is believed to be in order.

* * * * *

Dean L. Engelhardt et al.
Serial No. 08/046,004
Filed: April 9, 1993
Page 7 (Request for Reconsideration of Restriction Requirement
(And Election of Species) Under 37 C.F.R. §1.143-June 23, 1991)

SUMMARY AND CONCLUSION

Claims 204-233 are presented for further prosecution, the restriction requirement notwithstanding. No claims have been amended, added or cancelled by this response.

This response is accompanying a Petition To Revive An Unintentionally Abandoned Application Under 37 C.F.R. §1.137(b) and authorization for the fee therefor. The Patent and Trademark Office is hereby authorized to charge Deposit Account No. 05-1135 for any other fees in connection with the Petition or this response, and to credit any overpayment therein.

In view of the above discussion of the issues, Applicants respectfully submit that substantive examination of all the instant claims, 204-233, is in order. Should it be deemed helpful or necessary, the Examiner is respectfully invited to telephone the undersigned at (212) 856-0876 to discuss the subject application.

Respectfully submitted,



Ronald C. Fedus
Registration No. 32,567
Attorney for Applicants

ENZO DIAGNOSTICS, INC.
c/o Enzo Biochem, Inc.
575 Fifth Avenue (18th Floor)
New York, New York 10017
(212) 856-0876